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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|------------------------|----------------------|---------------------|---------------------------------------|
| 10/538,823 | 06/13/2005 | L Julie Huber | 13407-026US1 5992 | |
| 26161 | 7590 10/04/2006 | | EXAMINER . | |
| FISH & RICHARDSON PC | | | LEE, JAE W | |
| P.O. BOX 102 MINNEAPOL | 2 IS, MN 55440-1022 | | ART UNIT | PAPER NUMBER |
| | | | 1656 | · · · · · · · · · · · · · · · · · · · |

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|
| Office Action Comments | 10/538,823 | HUBER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Jae W. Lee | 1656 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim 11 apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE |). lely filed the mailing date of this communication. O (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | |
| | action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the n | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-21</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) <u>1-21</u> are subject to restriction and/or e | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3.☐ Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | _ | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) | 5) Notice of Informal P | | | | | |
| Paper No(s)/Mail Date | 6) Other: | | | | | |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, drawn to a method of evaluating a compound.

Group II, claim(s) 12, drawn to a method of evaluating a protein comprising determining whether the alteration has an effect on the interaction, of the polypeptide with a cytochrome c polypeptide, or on the deacetylation of cytochrome c.

Group III, claim(s) 13, drawn to a method of evaluating a protein comprising identifying one or more polymorphisms in a gene that encodes the candidate protein.

Group IV, claim(s) 14-16, drawn to a method of comprising evaluating the compound for its ability to modulate acetylation in the cell.

Group V, claim(s) 17-21, drawn to a method of modulating cell growth in an animal comprising modulating the acetylation of a cytochrome c in the animal.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical

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features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The technical feature that is shared among the Applicants' Groups of inventions drawn to different methods is a polypeptide having acetylation or deacetylation activity. Applicants use the technical feature in different methods of evaluating a compound, a protein, or in a method of modulating cell growth. Frye teaches human SIRT1, SIRT2, SIRT3, and many polypeptides having acetylation or deacetylation activity (R.A. Frye, Phylogenetic classification of prokaryotic and eukaryotic Sir2-like proteins. *Biochem. Biophys. Res. Commun.* 273 (2000), pp. 793–798, See attached reference). Therefore, the shared technical feature of the Groups is not a "special technical feature", and unity of invention between the Groups does not exist.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

SIRT1, SIRT2, and SIRT3

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-11 correspond to the species listed above wherein each method is directed to acetylation or deacetylation activities by a polypeptide, wherein the said polypeptide can be SIRT1, SIRT2, or SIRT3.

The following claim(s) are generic: 1-11.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the species, SIRT1, SIRT2, or SIRT3, is considered as a single inventive concept because each polypeptide is comprised of amino acids that fold into a different three-dimensional structure having different mode of operation, different function, or different effects (MPEP § 806.04, MPEP § 808.01).

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner: Jae W. Lee, Ph.D.

RICHARD HUTSON, PH.D. PRIMARY EXAMINER